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| APPLICATION NO.                              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/058,495                                   | 01/28/2002  | Richard King         | 265280-68002 2189   |                  |
| 23643 7590 09/17/2007 BARNES & THORNBURG LLP |             |                      |                     | IINER            |
| 11 SOUTH MERIDIAN                            |             |                      | RAMANA, ANURADHA    |                  |
| INDIANAPOLIS, IN 46204                       |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3733                |                  |
|  |             |                      |                     |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 09/17/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |  | $\mathcal{M}$   |             |  |  |  |  |
|--|--|---|-------------|--|--|--|--|
|  | Application No.  | Applicant(s)  |             |  |  |  |  |
| Office Action Commence   | 10/058,495   | KING ET AL.   |             |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |             |  |  |  |  |
|  | Anu Ramana   | 3733  |             |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence ad  | idress      |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | N. nely filed the mailing date of this o D (35 U.S.C. § 133). |             |  |  |  |  |
| Status   |  |   | •           |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>03 Ju</u>   | ılv 2007   |   |             |  |  |  |  |
| ,  | action is non-final.   | ٠   |             |  |  |  |  |
| 3)☐ Since this application is in condition for allowar   |  | secution as to the  | e merits is |  |  |  |  |
| closed in accordance with the practice under E   |  |   |             |  |  |  |  |
| Disposition of Claims  |  |   |             |  |  |  |  |
| 4)⊠ Claim(s) <u>49,50,52-54,125,126 and 128-132</u> is/are pending in the application.   |  |   |             |  |  |  |  |
| <b>4</b> a) Of the above claim(s) <u>53,54,130 and 131</u> is  | 4a) Of the above claim(s) 53,54,130 and 131 is/are withdrawn from consideration.   |   |             |  |  |  |  |
| 5) Claim(s) is/are allowed.  | 5) Claim(s) is/are allowed.  |   |             |  |  |  |  |
| 6)⊠ Claim(s) <u>49,50,52,125-126, 128-129 and 132</u> is/are rejected.   |  |   |             |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |   |             |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.  |   |             |  |  |  |  |
| Application Papers   |  |   |             |  |  |  |  |
| 9)☐ The specification is objected to by the Examine  | r.   |   |             |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>28 January 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.   |  |   |             |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |   |             |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |   |             |  |  |  |  |
| 11) ☐ The oath or declaration is objected to by the Ex   | caminer. Note the attached Office  | Action or form P  | 10-152.     |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |             |  |  |  |  |
| 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:  |  |   |             |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |   |             |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |   |             |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |   |             |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |   |             |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |   |             |  |  |  |  |
|  |  |   |             |  |  |  |  |
| Attachment(s)  |  |   |             |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |  |   |             |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Da  | ate   |             |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date   | 5)   | atent Application   |             |  |  |  |  |
|  |  |   |             |  |  |  |  |

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-50, 52, 125-126, 128-129 and 132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants' disclosure does not support a radiation crosslinked layer having a uniform degree of crosslinking.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 49-50, 52, 125-126, 128-129 and 132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 49 and 125, it is unclear how the radiation crosslinked layer can have a second side crosslinked to the same degree as the first side because the second side is melt fused with the non-crosslinked layer of polyethylene.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title; if the differences between the subject matter sought to be patented and the prior art

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are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49, 50, 52, 55, 125, 128-129 and 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devanathan et al. (US 5,645,594) in view of McKellop et al. (US 6,165,220).

Devanathan et al. disclose an acetabular cup or "implantable orthopedic prosthesis" or "laminar composite bearing" having multiple layers formed by compression molding under pressure and temperature wherein during molding the polymer (PMMA) melts and forms an inter-penetrating polymer network or "melt-fused" interface (Fig. 2 and col. 2, lines 10-65).

Devanathan et al. disclose all elements of the claimed invention except for an irradiated crosslinked polymer layer.

McKellop et al. teach irradiating the bearing surface of a UHMWPE cup using ebeam irradiation to produce cross-linking on its bearing or articulating surface for wear resistance (col. 7, lines 25-67, col. 8, lines 1-29 and col. 9, lines 19-31).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have irradiated the articulating surface of the Devanathan et al. bearing with e-beam irradiation, as taught by McKellop et al., to produce cross-linking on its articulating surface for wear resistance.

## Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on July 3, 2007 have been fully considered.

The Examiner disagrees that combining McKellop et al. with Devanathan et al. destroys Devanathan et al. Devanathan et al. disclose an acetabular cup having an articulating surface in a layer (zone 1) made of UHMWPE. McKellop et al. teach irradiating an articular surface of an acetabular cup to produce cross-linking for wear resistance. It would have been obvious to one of ordinary skill in the art to irradiate the

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articular surface (zone 1) of the Devanathan et al. composite bearing, as taught by McKellop et al., for increased wear resistance.

It is further noted that claim 125 only requires that the prosthesis have a first layer with a first degree of crosslinking and a second layer with a second degree that is different than the first degree. The Examiner notes that the second degree could be zero.

### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR September 10, 2007

ANURADHA RAMANA
ANURADHA EXAMINER
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700